

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 10/758,997
Inventor(s) : Michael Nyle Hershberger
Filed : January 16, 2004
Art Unit : 1616
Examiner : Nathan W. Schlientz
Docket No. : P-155
Confirmation No. : 7917
Customer No. : 27752
Title : Liquid Compositions Comprising One
or More Medicaments

APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
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This Brief is filed pursuant to the appeal from the decision communicated in the Office Action mailed on November 23, 2009.

A timely Notice of Appeal was filed on February 22, 2010.

REAL PARTY IN INTEREST

The real party in interest is The Procter & Gamble Company of Cincinnati, Ohio.

RELATED APPEALS AND INTERFERENCES

There are no known related appeals, interferences, or judicial proceedings.

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STATUS OF CLAIMS

Claims 1-19, 27-33, and 39 are pending in the application. Claims 8-14, 27-33, and 39 were previously withdrawn from consideration. Claims 1-7 and 15-19 have been rejected.

Claims 1-7 are appealed.

A complete copy of the appealed claims is set forth in the Claims Appendix attached herein.

STATUS OF AMENDMENTS

Claims 15 through 19 are cancelled, without prejudice, with this Appeal Brief to simplify issues on appeal.

SUMMARY OF CLAIMED SUBJECT MATTER

All references are, without limitation, to the specification as filed.

One embodiment of the present invention, as recited in independent claim 1, relates to a liquid composition (page 5, line 19). The liquid composition comprises beet pulp (page 23, line 1; Example 1 on page 24, line 15; Example 2, page 25, line 15; Example 3, page 26, line 12), a medicament (page 5, line 20), a flavorant (page 5, line 21) and water (page 5, line 22). The composition is essentially free of sugars (page 5, line 23) and is adapted for use by a companion animal (page 5, lines 23-24).

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

Ground 1: Whether claims 1 through 5 are allegedly unpatentable under 35 U.S.C. §103(a) over Chu (U.S. Publication No. 2002/0025325) in view of Burkhalter (The Journal of Nutrition, 2001), Sunvold (Journal of Animal Science, 1995), Fahey (Journal of Animal Science, 1990), Sunvold '258 (U.S. Patent No. 5,932,258), Jezek (Chemical and Biochemical Engineering Quarterly, 1996), and Desforges (U.S. Patent No. 5,252,136).

Ground 2: Whether claims 1 through 7 are allegedly unpatentable under 35 U.S.C. §103(a) over Tinembart (U.S. Publication NO. 2002/0058683) in view of Chu (U.S. Publication No. 2002/0025325), Burkhalter (The Journal of Nutrition, 2001), Sunvold (Journal of Animal Science, 1995), Fahey (Journal of Animal Science, 1990), Sunvold '258 (U.S. Patent No.

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5,932,258), Jezek (Chemical and Biochemical Engineering Quarterly, 1996), and Desforges (U.S. Patent No. 5,252,136).

ARGUMENTS

Ground 1: Independent Claim 1

Applicants respectfully submit that the rejection of claims 1 through 5 under 35 U.S.C. §103(a) over Chu (U.S. Publication No. 2002/0025325) in view of Burkhalter (The Journal of Nutrition, 2001), Sunvold (Journal of Animal Science, 1995), Fahey (Journal of Animal Science, 1990), Sunvold '258 (U.S. Patent No. 5,932,258), Jezek (Chemical and Biochemical Engineering Quarterly, 1996), and Desforges (U.S. Patent No. 5,252,136) is improper. Therefore, Applicants respectfully request reversal and withdrawal of the rejection and allowance of the claims.

Applicants submit that the factual analysis set forth in the Office Action is flawed. Applicants contend that the Examiner has failed to adequately make out a prima facie of obviousness by determining the scope and content of the prior art as required under Graham v. John Deere Co., 383 US 1, 148 USPQ 459 (1966). Furthermore, under MPEP § 2141.02 (I), in determining the differences between the prior art and the claims, the question under 35 USC § 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); Schenck v. Nortron Corp., 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983). Under MPEP 2141.02 (VI), a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). Moreover, MPEP § 2142 additionally states that the key to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court, in KSR Int'l v. Teleflex Inc., 550 U.S. 398, 82 USPQ2d 1385 (2007), noted that the analysis supporting a rejection under 35 U.S.C. § 103 should be made explicit. The Federal Circuit has stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). See also

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KSR. (quoting Federal Circuit statement with approval). Thus, the Examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness, which has not been done.

As best understood by Applicants, the Office Action is using Chu for the disclosure of an oral vaccination through drinking water or syrups comprising admixing a palatable flavorant with a vaccine formulation in order to promote self-administration of the vaccine formulation and/or to prevent rejection of the formulation when administered by an animal handler. (Office Action mailed November 23, 2009, page 3). The Office Action admits that Chu does not teach the addition of beet pulp to its composition (Office Action mailed November 23, 2009, page 4). However, to remedy that deficiency of Chu, the Office Action combines Chu with the disclosures of Burkhalter, Sunvold, Fahey, Sunvold '258, Jezek, and Desforges. (Office Action mailed November 23, 2009, page 4). The Office Action uses the disclosures of Burkhalter, Sunvold, Fahey, Sunvold '258, Jezek, and Desforges for the proposition that it would have been obvious for one of ordinary skill in the art at the time of the invention to add beet pulp fiber to the composition of Chu because beet pulp fiber is well-known as a commercial source of dietary fiber for use in pet foods. However, this line of reasoning fails because the combination, even if proper, does not result in a composition in accordance with the present claims, and such a combination is directly at odds with the disclosures of each of these secondary references.

Chu is directed to "methods and compositions both for providing protection against disease in an animal and for inducing increased intake of an orally administered vaccine by an animal." Abstract. Burkhalter is directed to an experiment "conducted to evaluate the effects of soybean hulls (SH) containing varying ratios of insoluble:soluble fiber (I:S) on nutrient digestibilities and fecal characteristics of dogs." Abstract. Sunvold discloses "two experiments were conducted to evaluate the addition of single sources and blends of dietary fibers to cat diets." Abstract. Fahey discloses the evaluation of the "optimal level of beet pulp (BP) inclusion in a meat-based dog diet and the effects of graded levels of dietary BP on fecal excretion responses and mean retention time of marked fiber in the gastrointestinal tract of the dog." Abstract. Sunvold '258 discloses that a "composition and process of use are provided to improve glucose metabolism in companion animals by controlling the postprandial glycemic response in those animals." Abstract. Jezek discloses that "[c]onsiderable quantities of dietary fibers are contained in sugar beet pulp as by products of saccharosse production." Abstract. Desforges

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discloses a “sugar composition consisting of from 90 to 99% by weight sugar and from 10 to 1% by weight of a non-gelling water-soluble dietary fibre.” Abstract.

In determining the differences between the prior art and the claims, the question under 35 USC § 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. Applicants submit that, even when combined, Chu, Burkhalter, Sunvold, Fahey, Sunvold ‘258, Jezek, and Deforges, however, fail to teach the liquid composition of the current application because the claimed invention as a whole would not have been obvious. Independent claim 1 of the present application is directed to, inter alia, a liquid composition comprising beet pulp, a medicament, a flavorant, and water, wherein the liquid composition is essentially free of sugars and is adapted for use by a companion animal. As noted in the Office Action and as best understood by Applicants, Chu fails to teach the addition of beet pulp to its composition. The Office Action is utilizing the disclosures of Burkhalter, Sunvold, Fahey, Sunvold ‘258, Jezek, and Deforges for the disclosure of beet pulp. As best understood by Applicants, Burkhalter, Sunvold, Fahey, and Sunvold ‘258 all disclose extruded and dried food compositions. Thus, even though Burkhalter, Sunvold, Fahey, and Sunvold ‘258 teach beet pulp, they are teaching the addition of beet pulp to extruded and dried food compositions, not to liquid compositions, and certainly not to liquid compositions comprising a medicament, a flavorant, and water, wherein that liquid composition is essentially free of sugars and is adapted for use by a companion animal. Thus, it is not a matter of using the disclosure of Chu and simply picking an ingredient from Burkhalter, Sunvold, Fahey, Sunvold ‘258 and adding it to the disclosure of Chu. Nothing in Burkhalter, Sunvold, Fahey, and Sunvold ‘258 even remotely suggests that beet pulp could be added to a liquid composition. These references are concerned with extruded and dried food compositions, which are entirely different from liquid compositions as disclosed in the present application. Thus, the Office Action has failed to consider the claimed invention as a whole and thus has failed to make out a proper 103(a) rejection of the claims.

Additionally, as best understood by Applicants, Jezek and Deforges disclose methods of production of dietary fibers from sugar beets, not the incorporation of beet pulp into pet compositions and not the incorporation of beet pulp into liquid compositions as claimed in independent claim 1.

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Moreover, as best understood by Applicants, Deforges discloses that the “object of the present invention is to provide a sugar composition.” Col. 2, lines 18 – 21. Deforges, therefore, is teaching away from the claims of the current application. As best understood by Applicants, the objective of Deforges is to produce a sugar composition whereas the claims of the current application are directed towards a liquid composition which is essentially free of sugars. “A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.” Tec Air Inc. v. Denso Manufacturing Michigan Inc., 192 F.3d 1353 (Fed. Cir. 1999).

In sum, as best understood by Applicants, Burkhalter, Sunvold, Fahey, Sunvold ‘258, Jezek and Deforges, either alone or in combination, all fail to teach the incorporation of beet pulp into a liquid composition such as claimed in the current application. As best understood by Applicants, Chu, Burkhalter, Sunvold, Fahey, Sunvold ‘258, Jezek, and Deforges, either alone or in combination, fail to teach a liquid composition comprising beet pulp, a medicament, a flavorant, and water wherein the compositions are essentially free of sugars. As best understood by Applicants, Chu, Burkhalter, Sunvold, Fahey, Sunvold ‘258, Jezek, and Desforges, either alone or in combination, fails to provide one of ordinary skill with a motivation to combine the references to arrive at the claims of the current application. Accordingly, Applicants respectfully request reconsideration.

Ground 1: Dependent Claims 2 through 5

With respect to dependent claims 2 through 5, the Office Action fails to specifically address even the expressly recited features of the pending dependent claims. Under the Office’s policy of compact prosecution, each claim should be reviewed for compliance with every statutory requirement for patentability in the initial review of the application, even if one or more claims are found to be deficient with respect to some statutory requirement. MPEP §707.07(g). It is submitted that the Office’s failure needlessly encourages piecemeal prosecution, which is to be avoided as much as possible. MPEP §707.07(g).

Accordingly, since no specific rejection of the recited features of the pending dependent claims has been given, Applicants respectfully request reconsideration based on the arguments submitted herein. Additionally, Applicants submit that the features recited in the dependent

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claims distinguish the present invention even more so than the features of independent claims and respectfully request the Appeal Board to give these additional features their own patentably weight.

However, in the event that the Appeal Board maintains the rejection of any of the dependent claims, Applicants respectfully request, in the interests of compact prosecution, that the Office apply art against each feature of each rejected dependent claim, on the record, and with specificity sufficient to support any rejection.

Ground 2: Independent Claim 1

Applicants respectfully submit that the rejection of claims 1 through 7 and 15 through 19 under 35 U.S.C. §103(a) over Tinembart (U.S. Publication NO. 2002/0058683) in view of Chu (U.S. Publication No. 2002/0025325), Burkhalter (The Journal of Nutrition, 2001), Sunvold (Journal of Animal Science, 1995), Fahey (Journal of Animal Science, 1990), Sunvold '258 (U.S. Patent No. 5,932,258), Jezek (Chemical and Biochemical Engineering Quarterly, 1996), and Desforges (U.S. Patent No. 5,252,136) is improper. Therefore, Applicants respectfully request reversal and withdrawal of the rejection and allowance of the claims.

Applicants submit that the factual analysis set forth in the Office Action is flawed. Applicants contend that the Examiner has failed to adequately make out a prima facie of obviousness by determining the scope and content of the prior art as required under Graham v. John Deere Co., 383 US 1, 148 USPQ 459 (1966). Furthermore, under MPEP § 2141.02 (I), in determining the differences between the prior art and the claims, the question under 35 USC § 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); Schenck v. Nortron Corp., 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983). Under MPEP 2141.02 (VI), a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). Moreover, MPEP § 2142 additionally states that the key to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court, in KSR Int'l v. Teleflex Inc., 550 U.S. 398, 82 USPQ2d 1385 (2007), noted that the analysis supporting a rejection under 35

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U.S.C. § 103 should be made explicit. The Federal Circuit has stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). See also KSR. (quoting Federal Circuit statement with approval). Thus, the Examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness, which has not been done.

As best understood by Applicants, the Office Action is using Tinembart for the disclosure of a veterinarian preparation, which can be oral dosage, for fleas comprising lufenuron and nitenpyram, wherein oral administration of a liquid composition comprising lufenuron and nitenpyram effectively controlled flea infestation. (Office Action mailed November 23, 2009, page 7). The Office Action admits that neither Tinembart nor Chu teaches the addition of beet pulp to its composition (Office Action mailed November 23, 2009, page 8). However, to remedy that deficiency of Tinembart and Chu, the Office Action combines these references with the disclosures of Burkhalter, Sunvold, Fahey, Sunvold '258, Jezek, and Desforges, as was previously done above with respect to Chu alone. (Office Action mailed November 23, 2009, page 8). The Office Action uses the disclosures of Burkhalter, Sunvold, Fahey, Sunvold '258, Jezek, and Desforges for the proposition that it would have been obvious for one of ordinary skill in the art at the time of the invention to add beet pulp fiber to the composition of Tinembart and/or Chu because beet pulp fiber is well-known as a commercial source of dietary fiber for use in pet foods. However, this line of reasoning fails because the combination, even if proper, does not result in a composition in accordance with the present claims, and such a combination is directly at odds with the disclosures of each of these secondary references.

Tinembart is directed to a:

veterinarian preparation for fleas is described, which consists of an amount that is effective against fleas of a combination of a compound of formula (I), wherein R₁ hydrogen, C₁-C₆-alkyl or C₃-C₇-cycloalkyl; R₂ is hydrogen, C₁-C₆-alkyl, or C₃-C₇-cycloalkyl; R₃ is hydrogen or C₁-C₆-alkyl; and A is heterocycle which is unsubstituted or substituted once or repeatedly by identical or different halogen atoms; and a compound of formula (II), wherein X is halogen, X₁ is hydrogen or halogen; X₂ is hydrogen or halogen; Y is partially or completely halogenated C₁-

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C₆-alkoxy which is interrupted by one oxygen atom, or partially or completely halogenated C₂-C₆-alkenyl; Y₁ is hydrogen or halogen; Y₂ is hydrogen or halogen; Y₃ is hydrogen or halogen; Z₁ is hydrogen or C₁-C₃-alkyl; and Z₂ is hydrogen or C₂-C₃-alkyl; and a physiologically acceptable formulation excipient.

Abstract. Tinembart, Chu, Burkhalter, Sunvold, Fahey, Sunvold '258, Jezek and Deforges, either alone or in combination, however, fail to teach the liquid compositions of the current application. Claim 1 is as noted above. The analysis and remarks submitted above are hereby incorporated by reference, are equally applicable here, and are relied on for distinguishing independent claim 1. Accordingly, Applicants respectfully request reconsideration.

Ground 2: Dependent Claims 2 through 7

With respect to dependent claims 2 through 7, the Office Action fails to specifically address even the expressly recited features of the pending dependent claims. Under the Office's policy of compact prosecution, each claim should be reviewed for compliance with every statutory requirement for patentability in the initial review of the application, even if one or more claims are found to be deficient with respect to some statutory requirement. MPEP §707.07(g). It is submitted that the Office's failure needlessly encourages piecemeal prosecution, which is to be avoided as much as possible. MPEP §707.07(g).

Accordingly, since no specific rejection of the recited features of the pending dependent claims has been given, Applicants respectfully request reconsideration based on the arguments submitted herein. Additionally, Applicants submit that the features recited in the dependent claims distinguish the present invention even more so than the features of independent claims and respectfully request the Appeal Board to give these additional features their own patentably weight.

However, in the event that the Appeal Board maintains the rejection of any of the dependent claims, Applicants respectfully request, in the interests of compact prosecution, that the Office apply art against each feature of each rejected dependent claim, on the record, and with specificity sufficient to support any rejection.

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SUMMARY

In view of all of the above, it is respectfully submitted that the rejections are improper. Accordingly, Applicants respectfully request reconsideration, reversal and withdrawal of the rejections, and allowance of the claims.

Respectfully submitted,
THE PROCTER & GAMBLE COMPANY

/Adam W. Borgman/
Adam W. Borgman
Registration No. 57,217
(513) 983-7422

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CLAIMS APPENDIX

1. A liquid composition comprising:

beet pulp;

a medicament;

a flavorant; and,

water;

wherein said composition is essentially free of sugars and is adapted for use by a companion animal.
2. The liquid composition in accordance with claim 1 comprising at least about 50% water, by weight of said composition.
3. The liquid composition in accordance with claim 1 comprising at least about 80% water, by weight of said composition.
4. The liquid composition in accordance with claim 1 comprising from about 0.00001% to about 99% of said medicament, by weight of said composition.
5. The liquid composition in accordance with claim 4 having a pH of from about 3 to about 7.
6. The liquid composition in accordance with claim 4 wherein the medicament is selected from the group consisting of: imidacloprid, nitenpyram, lufenuron, fipronil, milbemycin oxime, and combinations thereof.
7. The liquid composition in accordance with claim 4 wherein the medicament is selected from the group consisting of: moxidectin, ivermectin, pyrantel, milbemycin oxime, lufenuron, selamectin, and combinations thereof.

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EVIDENCE APPENDIX

None.

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RELATED PROCEEDINGS APPENDIX

None.